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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/847,519

05/01/2001

Ralf M. Luche

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02/09/2004

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EXAMINER

NASHED, NASHAAT T

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 02/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/847,519

Applicant(s)

LUCHE ET AL.

Examiner

Nashaat T. Nashed

Art Unit

1652

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 12 January 2004. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 6-10 and 11-114.

Claim(s) withdrawn from consideration: _____

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____



Nashaat T. Nashed
Primary Examiner
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Claims 6-10 and 12-14 are pending and under consideration.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-10 and 12-14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth in the prior Office actions mailed 3/6/02, 12/4/02, and 8/12/03.

Claims 6-10 and 12-14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

In response to the above rejections, Applicants reiterated their previous arguments and argue that the prior Office action has not set forth a *prima facie* case showing that the subject matter of the instant claims, i. e., polynucleotide encoding a Dual Specificity Phosphatase-14 (DSP-14) polypeptide lacks utility. In addition, they have filed a declaration by Dr. Ralf M. Luche showing that the polypeptide of SEQ ID NO: 2 catalyzes the hydrolysis of highly active phosphate ester named 6,8-difluoro-4-methylumbelliferyl phosphate (also known as 6,8-difluoro-4-methyl-7-O-phosphocumerin). Also, Dr. Luche provides an expert contradictory opinion about the enzymatic activity of SEQ ID NO: 2 in U. S. Patent 6,268,135.

Applicants' arguments filed 1/12/04 have been fully considered but they are not deemed to be persuasive. The examiner disagrees with applicants' arguments and declaration. The rejection of the claimed above is based on two issues. The first is the credibility of the applicants' asserted non-specific utility of phosphatase. The second issue contends that even if the applicants' asserted and questionable utility is accepted, the specification fails to identify a specific or substantial utility for the nucleic acid or the polypeptide in the instant application.

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The asserted non-specific utility remains questionable even in light of Dr. Luche's declaration. The chemically reactive cumerin derivative used to assay for the activity of the polypeptide of SEQ ID NO: 2 is a non-specific substrate, and cannot distinguish between a protein phosphatase and a phospholipase, or any other phosphatase activity for that matter. So, the mere fact that the polypeptide of SEQ ID NO: 2 catalyzes the hydrolysis 6,8-difluoro-4-methylumbelliferyl phosphate is not sufficient evidence *per se* to indicate a phosphatase activity, let alone dual specificity protein phosphatase activity.

As indicated in the previous Office actions, a *prima facie* case of lack utility has been established, explaining by sound scientific reasoning and support from the art why a person of ordinary skill in the art would doubt that the asserted and specific utility of the amino acid sequence of SEQ ID NO: 2. Applicants have presented no evidence or, indeed, any arguments to establish that the specification established both a well-established and substantial utility. Applicants merely identify several statements in the specification, which have been considered by the examiner. They further argue, "one of ordinary skill in the art would know the uses of DSP-14".

Applicants make no effort to explain why they consider the disclosure of some conserved fragment is sufficient to establish a specific and substantial utility. Applicants' assertions that both U. S. Patent 6,258,582 (582) and 6,132,964 (964) support their asserted utility, and the phospholipase disclosed by Acton in U. S. Patent 6,268,135 (135) has not been demonstrated to have a phospholipase activity are misplaced. The 135 patent is an issued patent and therefore, it is presumed to be valid under 35 U. S. C. 282, and the claims is directed to nucleic acid encoding the polypeptide of SEQ ID NO: 2. The utility stated in the 135-patent is a phospholipase. Since the patent is issued based on a phospholipase utility, it would be improper for the examiner to comment on that utility for the polypeptide of SEQ ID NO: 2. Applicants are reminded that they have not demonstrated any dual specificity protein phosphatase activity for the polypeptide of SEQ ID NO: 2 of the instant application. Since the phospholipase utility for the protein in the 135-patent is presumed to be a credible utility and valid, the argument set forth in the prior Office action remains valid. As for Dr. Ralf M. Luche opinion about the catalytic activity of the polypeptide of SEQ ID NO: 2 of the 135-patent, it represents a mere speculation without solid experimental facts. With regard to the 582 and 964, the application identified dual specificity phosphatase as a distinct family of enzymes from those of Ser/Thr-phosphatase and Tyr-phosphatases. Thus, the presence of the homologous domains in other enzymes is not sufficient diagnostic feature for a specific family of enzymes. Conclusory statements unsupported by evidence or scientific reasoning are insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action. On page 5, second paragraph, applicant elude to a declaration that will address U. S. patent 6,268,135. There is no declaration accompanied applicants response. Once again, applicant should be reminded with the validity of U. S. patent 6,268,135.

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on 571-272-0928. The fax phone numbers for this Group are 703-305-3014 and 703-308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.